109TH CONGRESS
2D SESSION

S. 3981

To amend the Federal Food, Drug, and Cosmetic Act to establish requirements for certain petitions submitted to the Food and Drug Administration, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 28, 2006

Mr. KOHL (for himself and Mr. LEAHY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish requirements for certain petitions submitted to the Food and Drug Administration, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Citizen Petition Fairness and Accuracy Act of 2006''.

SEC. 2. CITIZEN PETITIONS AND PETITIONS FOR STAY OF AGENCY ACTION.

Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended by adding at the end the following:

''(G)(i) Notwithstanding any other provision of law, any petition submitted under section 10.30 or section 10.35 of title 21, Code of Federal Regulations (or any successor regulation), shall include a statement that to the petitioner's best knowledge and belief, the petition—

''(I) includes all information and views on which the petitioner relies, including all representative data and information known to the petitioner that is favorable or unfavorable to the petition;

''(II) is well grounded in fact and is warranted by law;

''(III) is not submitted for an improper purpose, such as to harass or cause unnecessary delay (including unnecessary delay of competition or agency action); and

''(IV) does not contain a materially false, misleading, or fraudulent statement.

''(ii) The Secretary shall investigate, on receipt of a complaint, a request under clause (vi), or on its own initiative, any petition submitted under such section 10.30 or section 10.35 (or any successor regulation), that—

''(I) does not comply with the requirements of clause (i);

''(II) may have been submitted for an improper purpose as described in clause (i)(III); or

''(III) may contain a materially false, misleading, or fraudulent statement as described in clause (i)(IV).

''(iii) If the Secretary finds that the petitioner has knowingly and willingly submitted the petition for an improper purpose as described in clause (i)(III), or which contains a materially false, misleading, or fraudulent statement as described in clause (i)(IV), the Secretary may—

''(I) impose a civil penalty of not more than $1,000,000, plus attorneys fees and costs of reviewing the petition and any related proceedings;

''(II) suspend the authority of the petitioner to submit a petition under such section 10.30 or section 10.35 (or any successor regulation), for a period of not more than 10 years;

''(III) revoke permanently the authority of the petitioner to submit a petition under such section 10.30 or section 10.35 (or any successor regulation); or

''(IV) dismiss the petition at issue in its entirety.

''(iv) If the Secretary takes an enforcement action described in subclause (I), (II), (III), or (IV) of clause (iii) with respect to a petition, the Secretary shall refer that petition to the Federal Trade Commission for further action as the Federal Trade Commission finds appropriate.

''(v) In determining whether to take an enforcement action described in subclause (I), (II), (III), or (IV) of clause (iii) with respect to a petition, and in determining the amount of any civil penalty or the length of any suspension imposed under that clause, the Secretary shall consider the specific circumstances of the situation, such as the gravity and seriousness of the violation involved, the amount of resources expended in reviewing the petition at issue, the effect on marketing of competing drugs of the pendency of the improperly submitted petition, including whether the timing of the submission of the petition appears to have been calculated to cause delay in the marketing of any drug awaiting approval, and whether the petitioner has a history of submitting petitions in violation of this subparagraph.

''(vi)(I) Any person aggrieved by a petition filed under such section 10.30 or section 10.35 (or any successor regulation), including a person filing an application

under subsection (b)(2) or (j) of this section to which such petition relates, may request that the Secretary initiate an investigation described under clause (ii) for an enforcement action described under clause (iii).

''(II) The aggrieved person shall specify the basis for its belief that the petition at issue is false, misleading, fraudulent, or submitted for an improper purpose. The aggrieved person shall certify that the request is submitted in good faith, is well grounded in fact, and not submitted for any improper purpose. Any aggrieved person who knowingly and intentionally violates the preceding sentence shall be subject to the civil penalty described under clause (iii)(I).

''(vii) The Secretary shall take final agency action with respect to a petition filed under such section 10.30 or section 10.35 (or any successor regulation) within 6 months of receipt of such petition. The Secretary shall not extend such 6-month review period, even with consent of the petitioner, for any reason, including based upon the submission of comments relating to a petition or supplemental information supplied by the petitioner. If the Secretary has not taken final agency action on a petition by the date that is 6 months after the date of receipt of the petition, such petition shall be deemed to have been denied on such date.

''(viii) The Secretary may promulgate regulations to carry out this subparagraph, including to determine whether petitions filed under such section 10.30 or section 10.35 (or any successor regulation) merit enforcement action by the Secretary under this subparagraph.''.

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